UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, Washington 98101-3140

October 17, 2008

Reply To: OEA 095

MEMORANDUM

SUBJECT: Summary of Comments from EPA Reviewers on "Draft Risk Assessment Approach for Evaluating Potential Risks from Consuming Breast-Milk for the Portland Harbor Superfund Site"

FROM: Dana Davoli
OEA

TO: File

On August 11, 2008, Michael Cox and I e-mailed a copy of "Draft Risk Assessment Approach for Evaluating Potential Risks from Consuming Breast-Milk for the Portland Harbor Superfund Site" ("Draft PH Breast Milk Approach") to the following EPA staff for review:

Dawn Ioven/R3/USEPA/US@EPA, Jacqueline Moya/DC/USEPA/US@EPA, Jon Reid/CI/USEPA/US@EPA, Marian Olsen/R2/USEPA/US@EPA, Milt Clark/R5/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Nancy Rios-Jafolla/R3/USEPA/US@EPA, Matthew Lorber/DC/USEPA/US@EPA, Daniel Stralka/R9/USEPA/US@EPA, Margaret McDonough/R1/USEPA/US@EPA

We also included a cover letter that provided some background on the PH site and asked for feedback on several specific issues.

On September 11, 2008, a conference call was held to get verbal feedback on the Draft PH Breast Milk Approach. All of the EPA reviewers except Daniel Stralka and Margaret McDonough were present. In addition the following EPA Region 10 staff was on the call: Eric Blischke, Michael Cox, Marcia Bailey, and Dana Davoli. The call was separated into two discussions, technical and policy. For the first half of the call on technical issues, Mike Poulsen from ODEQ was present. Written comments were received from only three reviewers, Jacqueline Moya, Matt Lorber (preliminary comments), and Daniel Stralka.

Below is a summary of the comments received either during the conference call or the in written form. It should be noted that the next draft of the PH Breast Milk Approach will be modified such that it is not specific for the Portland Harbor site but rather is

a general approach that can be used at any site. In addition, information as to how to use the approach for chemicals in addition to PCBs (e.g. chlorinated dioxins/furans, DDX) will be added.

(A) TECHNICAL ISSUES:

(1) General

Comparison of calculated breast milk PCB concentrations in the Draft PH Breast Milk Approach to literature values

Several reviewers thought the equations and models that we used were appropriate while others questioned if they were realistic. A majority of people thought we should ground-truth the models/equations used in the Draft PH Breast Milk Approach methodology document by comparing our predicted breastmilk PCB concentrations to those found in the literature. Some of this literature information on PCB levels in breastmilk is already provided in the OR DHS/ATSDR Public Health Consultation Letter on Breastfeeding that was sent to the PH RPMs. This letter includes a discussion of the health benefits from breast-feeding, a summary of concentrations of PCBs found in breastmilk in the literature, as well as information on effects levels in human studies. This letter was not included in the material sent to the EPA reviewers, but will be attached to future versions of the Draft PH Breast Milk Approach document. In addition, an additional literature search will be done to ensure that the Public Health Consultation Letter includes all of the relevant measured concentrations of PCBs in human milk in the literature.

The highest PCB concentration measured in breast milk that OR DHS was able to find in the literature was 15 µg/g-lipid, lower than the 24 µg/g-lipid estimated using the example PCB calculation in the Draft PH Breast Milk Approach (assuming 1 ppm in bass and a fish ingestion rate of 142 g/day). If the decrease in PCB concentrations in breast milk over a year of breastfeeding is included as a part of the PCB example (see Exposure below), the PCB concentration estimated in breast milk will be about 18 µg/g-lipid. However, as discussed below (see Exposure below), the newly revised human milk chapter of EPA's Child-Specific Exposure Factors Handbook provides data on human milk intake for four age groups under 1 year of age: birth to <1 month, 1 to <3 months, 3 to <6 months, and 6 to <12 months. One reviewer recommended calculating the intake for each of these age group instead of one average for the 1 year old. When this is done, the concentration of PCBs in breast milk using the example PCB calculation in the PH document (assuming 1 ppm in bass and a fish ingestion rate of 142 g/day) is about MIKE__ µg/g-lipid.

The dose to the infant estimated for the PCB example in the PH document is approximately 30 times that of the dose to the mother. This would be expected for not only PCBs but for other bioacummulative compounds. This estimate is consistent with EPA's Draft Dioxin Reassessment that states that, "*The intake to breast-fed children was estimated to be between 1 and 2 orders of magnitude higher than adults, on a body weight basis…..* (page 4-39, Volume 2) and with a recent EHP article (Contaminants in

Human Milk Weighing the Risks against the Benefits of Breastfeeding, October, 2008) that states that, *"A review by certified nurse–midwife Joanne Jorissen in the October 2007 Advances in Neonatal Care notes that on average, the nursling receives about 50 times (per kilogram of body weight) the daily PCB intake of adults…"*

(2) Toxicity

Adequacy of the ATSDR intermediate MRL as the toxicity value of choice

There were several question and comments on use of the ATSDR MRL. Several of these came from reviewers who were unfamiliar with the Rice et al monkey study that the MRL was based upon. For example, questions were raised as to whether the PCB congener mixture tested in monkeys reflected what is actually seen in mother's milk (the mixture used in the monkey study represented 80% of the congeners present in breastmilk in Canadian women, in a proportional mixture) and if the study included both in utero exposure and infant exposure from breastfeeding (the study included exposure to infant monkeys only and did not include in utero exposure).

Other issues raised were:

Does the mixture of PCB congeners used in the monkey study reflect the congeners present at the PH site? For the PH site, the PCB congeners present in fish vary by species and river mile. For example, for small mouth bass, from 44% to 54% of the congener mass is represented by the 15 congeners used in the monkey study. However, the percent contribution of each congener to this mass at PH was often very different than the percent of that congener in the monkey study. For example, PCB congener 118 represented 12.8% of the mass fed to the monkeys, while the percent contribution of this congener to total mass in the PH bass samples ranged from 2.5% to 12.4% by river mile. Although this is an uncertainty for the breastfeeding scenario, it is not unique to this scenario. For example, the cancer and non-cancer chronic risks from consuming fish are calculated using EPA's cancer slope factor and RfD for Aroclors with Aroclor concentrations in fish tissue. This is done despite the fact that the congener pattern in fish tissue vary from site to site and within a site. In addition, data have shown that due to environmental fate and transport issues (e.g., degradation, bioaccumulation) congener patterns in fish do not reflect the congener pattern of the commercial Aroclors used in developing the PCB cancer slope factor and the RfD.

Were the dioxin-like PCB congeners and chlorinated dioxins and furans that might be present at the PH site represented in the toxicity mixture? Does the PCB MRL take into account exposures to dioxin-like toxicity from these compounds? Approximately 24% of the mixture fed to the monkeys was composed of 5 of the dioxin-like PCB congeners: PCB105, PCB118, PCB156, PCB157, and PCB189. The percentage of these 5 congeners in the bass samples at PH ranged from 4.6% to 19% by river mile. Other dioxin-like PCB

congeners are present in fish at PH but were not represented in the mixture fed to the monkeys. The mixture fed to the monkeys also did not include chlorinated dioxins and furans. Therefore, the PCB MRL would not account for exposure to some of the dioxin-like congeners in PH fish nor for the chlorinated dioxins and furans in these fish. Exposure to these compounds at the PH would need to be done using toxicity value specific for 2, 3, 7, 8- TCDD and would add to the risk estimated for PCBs. This calculation for dioxin-like toxicity will be done in the next draft of the Breast Milk Approach.

Exposure

As a part of the PH breastmilk document, an example using some of the exposure assumptions from the PH site was presented (e.g., it was assumed that the chemical concentration in fish was 1 ppm and that the fish ingestion rate was 142 g/day). Some reviewers questioned the source of these assumptions, if they were average or high end exposures, and if they were overly conservative. It also was not clear that this was just an example PCB calculation for breastfeeding for this document and that many other exposure routes were being considered in the HHRA for the PH site. To deal with these issues, the PH methodology document will be rewritten such that it is not specific for PH, provides more generic guidance for all sites, and is clear that the example provided is just an example.

It was suggested that the expected body burden reduction of PCBs (i.e., concentration of PCBs in mother's milk over the year of breastfeeding) should be included in both the Risk Characterization and Uncertainty Sections. This will be done. This would reduce the PCB concentration estimated in breast milk from the 24 µg/g-lipid estimated using the example PCB calculation in the PH document (assuming 1 ppm in bass) to about 18 µg/g-lipid.

Maternal dietary intake of PCBs during pregnancy and lactation is only weakly correlated with PCB concentrations in human milk. The more important determinant is long-term consumption of PCBs by the mother. For the PH document, it was assumed that steady-state conditions exist and that maternal intake occurs over a time-period greater than the PCB half-life which is consistent with EPA's Combustion Guidance and with equations 1 through 3(b) in Section 3.4.4.2 of the ATSDR *Toxicological Profile*. Several people pointed out that because of this, the estimates made in the PH document are very sensitive to the half-life assumed for PCBs (7 years in the PH document) as well as to the number of years that the mother is exposed before breast-feeding. It was recommended that these two issues will be specifically addressed in more detail in the Uncertainty Section. More discussion will be included to show how the PCB half-life was chosen and how changes in the half-life affect the calculations. In addition, calculations will be done in the Uncertainty Section to show how reductions in the mother's exposure affect the dose to the infant. For example, if it is assumed that mother is exposed for only 7 years (equivalent to the PCB half life), dose to the infant is reduced by one-half.

The newly revised human milk chapter of EPA's Child-Specific Exposure Factors Handbook September, 2008) provides data on human milk intake for four age groups under 1 year of age: birth to <1 month; 1 to <3 months; 3 to <6 months; and 6 to <12 months. One reviewer recommended calculating the intake for each of these age group instead of using one average value for the 1 year old. When the calculation using the four age groups is done, the concentration of PCBs in breast milk using the example PCB calculation in the PH document (assuming 1 ppm in bass and a fish ingestion rate of 142 g/day) is about __ µg/g-lipid. The next draft of the human milk methodology document will use the latest information from the Child-Specific Exposure Factors Handbook to calculate exposure to the breast fed child.

Risk Characterization

EPA's Combustion Guidance recommends using an averaging time of 1 year for both the cancer and non-cancer exposure calculations for the infant, but states that using a 1 year averaging time for cancer may overestimate the average daily intake by "almost two orders of magnitude". For the PH Human Milk Methodology document, the averaging time was assumed to be 1 year for non-cancer effects. For cancer risk, the averaging time was assumed to be 70 years. Some commenters were still concerned about the validity of calculating cancer risk for an exposure duration of 1 year, even when an averaging time of 70 years is used. The cancer risk calculation using an averaging time of 70 years will be included in the next draft of the human milk methodology document and the uncertainties in this calculation will be acknowledged.

Uncertainty Section

There was a general consensus that this section should be expanded. There was also a suggestion that it include additional sensitivity analyses for several parameters. Some of the issues that merited additional uncertainty discussion were half-life, the mother's exposure in relation to half-life, and site specific data on PCB congeners versus the mixture of congeners fed to the monkeys in the Rice study. It was also recommended that the breastfeeding sections in the latest draft of EPA's draft Dioxin Reassessment be reviewed to determine what other parameters should be discussed in more detail in the Uncertainty Section. All of these recommendations will be addressed.

The Uncertainty Section included an example where the non-cancer intake for a child was calculated for seven years of exposure assuming that one year of exposure was from breastfeeding and six years was from fish consumption. The calculated exposure for 7 years on a mg/kg/day basis is lower than that for the one year of breastfeeding. There was some confusion as to why this difference occurs. A suggestion was made that the discussion on this difference be clarified. HQs were then calculated using EPA's RfD with the daily intake from one year of exposure from breastfeeding and seven years of exposure (one year from breastfeeding and 6 from fish consumption). Given our confidence in the use of the PCB ATSDR MRL and the confusion in differences between intakes from a one versus seven year exposure duration, we will not include the seven years exposure calculation and comparison of HQs calculated using EPA's PCB RfD.

One reviewer also suggested that the intake from 30 years of exposure be calculated to show that the body burden calculated from 30 years would not be significantly different from one year of breastfeeding. This comment shows that additional discussion may be needed in the document to clarify why it is important to calculate the non-cancer risks to breastfeeding infants independent of other exposure scenarios.

(B) POLICY AND RISK MANAGEMENT/RISK COMMUNICATION ISSUES

Although the methodology and most of the exposure parameters for the mother's milk pathway are in existing EPA guidance, there was concern that adding this scenario to Superfund and RCRA risk assessments is precedence setting. Because of this, some of the reviewers suggested that we should consider having the document peer reviewed and that we ask for input from other EPA programs. It wasn't clear how we could ask for peer review and program input on guidance that EPA has already published (e.g., U. S. EPA Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities (Combustion Guidance), U.S. EPA. Child-Specific Exposure Factors Handbook) and that has been used for several years to assess risks, at least for hazardous waste combustion incinerators. We are not proposing the use of any new methods but rather extending the combustion guidance to assessment of the breastmilk pathway at other hazardous waste sites.

Several reviewers were concerned about the risk communication issues and outreach related to this pathway including the need to discuss the benefits from breastfeeding and from consumption of fish with low contaminant levels. The PH document that was sent out to the EPA reviewers did not include the OR DHS/ATSDR Public Health Consultation Letter on Breastfeeding as we were primarily concerned with comments on the methodology and parameters used to calculate intake from breastfeeding and the cancer and non-cancer risks. The OR DHS/ATSDR letter includes a discussion of the health benefits from breast-feeding, a summary of concentrations of PCBs found in breastmilk in the literature as well as information on effects levels in human studies. Recommendations were also made for a community outreach program. To demonstrate that risk communication issues and outreach are an integral component of the human risk We recognized this as a major concern and are proposing to deal with it by requiring that the benefits of breastfeeding be included in the risk assessment and by working with OR DHS in developing a community outreach campaign directed toward girls and women of child-bearing age who are high fish consumers. These issues were not included in the PH mother's milk methodology document so it was not clear that we had considered them. It may be useful to include a summary in the breastmilk methodology document of the risk-benefit discussion in OR DHS/ATSDR as well as a summary of the recommended outreach activities or to include the OR DHS Public Health Consultation Letter on Breastfeeding to the methodology paper.

Given the concern with the risk communication issues and the fact that this pathway will not drive the remedial goal for the PH site, Eric Blischke asked whether there is really a need to include this pathway, at least in the PH HHRA. This is a separate question from a

decision to develop Region 10 OEA guidance on the breastmilk pathway that would be used for all Superfund and RCRA sites. For some sites, this pathway may be the driver for remediation.